

## 5 We Claim:

1. A pharmaceutical composition as bilayered tablet comprising:

(a) a first discrete zone made with Formulation (A) which comprises; a therapeutically effective amount of antihistaminic drug or, a pharmaceutically accepted salt thereof in an amount from about 10% to about 30% preferably in an amount of about 15% to about 25%, and a first carrier base material, the first carrier base material comprising, a mixture of;

(iv) one or more fillers selected from cellulose derivatives in an amount from about 20% to about 45% preferably in an amount of about 30% to about 45%, starch derivatives in an amount from about 5% to about 25% preferably in an amount of about 10% to about 20%, polyols in an amount from about 10% to about 30% preferably in an amount of about 10% to about 20%, by weight of Formulation (A),

(v) an at least one disintegrant in an amount from about 4% to about 15% preferably in an amount of about 6% to about 10%, by weight of Formulation (A),

(vi) an at least one pharmaceutically accepted glidants or lubricants in an amount from about 0.2% to about 3%, by weight of Formulation (A),

20 wherein, the first carrier base material provides an immediate release of the antihistaminic drug and a pharmaceutically accepted salts thereof; and

(b) a second discrete zone made with Formulation (B) which comprises; a therapeutically effective amount of a decongestant drug or, a pharmaceutically accepted salt thereof in an amount from about 20% to 40% preferably in an amount of about 25% to about 35%, and a second carrier base material, the second carrier base material comprising, a mixture of;

(iii) an at least one sustained release compound in an amount from about 40% to 80% preferably in an amount of about 60% to about 75% by weight of Formulation (B),

(iv) an at least one pharmaceutically accepted glidants or lubricants in an amount from about 0.2% to about 4%, by weight of Formulation (B),

30 wherein, the second carrier base material provides the sustained release of decongestant drug or pharmaceutically accepted salts thereof.

2. The composition of claim 1 wherein:

Formulation (A) comprises;

(i) the cellulose derivatives selected from the group consisting of microcrystalline cellulose, powdered cellulose, the starch derivatives selected from the group consisting of corn starch, potato starch, pregelatinized starch, the polyols selected from the group consisting of mannitol, xylitol,

(ii) the disintegrant selected from the group consisting of crosscarmellose sodium, sodium starch glycolate, corsslinked polyvinylpyrrolidone,

- 5 (v) an at least one pharmaceutically accepted glidants or lubricants selected from any of talc, magnesium stearate or colloidal silicon dioxide, and;

Formulation (B) comprises;

- (i) the sustained release compound selected from the group consisting of Kollidon SR, Ethyl cellulose, Sodium alginate, Chitosan, Carbopol, or Xanthan gum,
- 10 (ii) an at least one pharmaceutically accepted glidants or lubricants selected from talc, magnesium stearate or colloidal silicon dioxide.

3. The formulation as in any of claims 1 or 2 wherein:

- (a) Formulation (A) comprises a novel crystalline Form A of Fexofenadine hydrochloride, characterized by the following X-ray powder diffraction pattern (d values in Å): 23.11, 11.50, 8.29, 7.03, 6.67, 6.16, 6.02, 5.75, 5.43, 5.33, 5.07, 4.69, 4.63, 4.44, 4.20, 4.15, 4.07, 3.55, and 3.44 and;
- 15 (b) Formulation (B) comprises Pseudoephedrine hydrochloride.

4. The formulation as in any of claims 1 or 2 wherein;

- (a) Formulation (A) comprises a novel crystalline Form X of Fexofenadine hydrochloride characterized by characterized by the following X-ray powder diffraction pattern (d values in Å): 16.05, 12.98, 8.29, 8.06, 6.25, 5.97, 5.54, 5.41, 4.89, 4.70, 4.55, 4.37, 4.32, 4.15, 4.03, 3.80, 3.67, 3.57, 3.42, and;
- 20 (b) Formulation (B) comprises Pseudoephedrine hydrochloride.

5. The formulation as in any of claims 1-4 comprising, Fexofenadine hydrochloride in an amount of about 60 mg and Pseudoephedrine hydrochloride in an amount of about 120 mg.

25

6. The composition of claims 1 or 2 wherein;

the first carrier base material comprises powered cellulose, corn starch, mannitol, crosscarmellose sodium, magnesium stearate and colloidal silicon dioxide in an amount from about 36.33%, 14.56%, 17.56%, 8%, 1% and 2.06% respectively by weight of Formulation (A).

30 7. The composition of claims 1 or 2 wherein;

the second carrier base material comprises, Kollidon SR, magnesium stearate and colloidal silicon dioxide in an amount from about 67.5%, 1.125% and 1.375% respectively by weight of Formulation (B).

8. The composition as in any of claims 6 or 7 comprising;

35 Fexofenadine hydrochloride in an amount of about 60 mg and Pseudoephedrine hydrochloride in an amount of about 120 mg.

9. The composition of claims 1 or 2 wherein, formulation (A) comprises, the antihistaminic drug is selected from any of the group consisting of Loratadine, Terfenadine, Cetrizine or a pharmaceutically accepted salts thereof.

40

5 10. A method of making bilayered tablet according to claim 1 comprising the steps of:

performing the operation in two separate steps comprising step (A) and step (B),

wherein step (A) comprises;

- 10 (i) sifting of Fexofenadine hydrochloride, powdered cellulose, mannitol, crosscarmellose sodium and colloidal silicon dioxide through #20 screen, sifting of corn starch and iron oxide red through mesh #80 screen,
- (ii) mixing the content of step (i) in rapid mixer granulator for about 25 minutes,
- (iii) mixing the content of step (ii) with isopropyl alcohol to obtain wet mass,
- (iv) drying the content of step (iii) in fluidized bed dryer followed by sifting and milling using a mechanical sifter and a comminuting mill, the comminuting mill comprising a screen of
- 15 1.5 mm, and;
- (v) alternatively sifting powdered cellulose, mannitol, corn starch, colloidal silicon dioxide and crosscarmellose through 20 # screen, sifting of colloidal silicon dioxide and crosscarmellose through mesh #40,
- (vi) mixing the dried content of step (iv) with the content of step (v) in double cone blender for
- 20 about 10 minutes,
- (vii) sifting magnesium stearate through mesh # 40 screen and mixing with the content of step (vi) in suitable blender for about 5 minutes;

wherein, step (B) comprises;

- 25 (i) sifting of Pseudoephedrine hydrochloride, Kollidon SR and colloidal silicon dioxide through #40 screen,
- (ii) mixing the content of step (i) in suitable blender for about 20 minutes,
- (iii) sifting of magnesium stearate through mesh #40 screen, mixing said sifted magnesium stearate with content of step (ii) in suitable blender for about 5 minutes, and;

compressing the material of step (A) and step (B) into tablets.

30 11. The method of claim 10 wherein:

step (A) comprises;

Fexofenadine hydrochloride Form A, mannitol, powdered cellulose, corn starch, colloidal silicon dioxide in an amount of about 60mg, 54mg, 108 mg, 43mg and 6.5mg respectively by weight of formulation (A).

35 wherein, step (B) comprises;

Pseudoephedrine hydrochloride, Kollidon, colloidal silicon dioxide and magnesium stearate in an amount of about 120mg, 270mg, 5.5mg, 4.5mg respectively by weight of formulation (B).

12. The method of claim 10 wherein:

40 step (A) comprises;

5 Fexofenadine hydrochloride Form X, mannitol, powdered cellulose, corn starch, colloidal silicon dioxide in an amount of about 60mg, 54mg, 108 mg, 43mg and 6.5mg respectively by weight of formulation (A).

wherein, step (B) comprises;

10 Pseudoephedrine hydrochloride, Kollidon, colloidal silicon dioxide and magnesium stearate in an amount of about 120mg, 270mg, 5.5mg, 4.5mg respectively by weight of formulation (B).

13. The formulation of claim 12 wherein, the bilayered tablet is coated with the suitable coating agents.

14. The formulation of any of claims 1-11 as bilayered tablet.

15 15. The formulation of claim 14 wherein, the bilayered tablet is coated with the suitable coating agents.

16. The formulation as in any of claims 12-15 wherein bilayered tablet is prepared by direct compression technique.

17. A method of treating mammalian animal in need of such a treatment using the composition of any  
20 of claims 1-14.